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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
INTE0004-100

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on **December 18, 2006**

Signature Doreen Yatko Trujillo

Typed or printed Name **Doreen Yatko Trujillo, Reg. No. 35,719**

Application Number	Filed
10/032,311	**December 21, 2001**

First Named Inventor
Robert W. Doms et al.

Art Unit	Examiner
1648	**Jeffrey S. Parkin**

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
  See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
  (Form PTO/SB/96)
- ☒ attorney or agent of record.
  Registration number **35,719**
- ☐ attorney or agent acting under 37 CFR 1.34.
  Registration number _____

Doreen Yatko Trujillo
Signature

Doreen Yatko Trujillo
Typed or printed name

(215) 665-5593
Telephone number

December 18, 2006
Date

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DOCKET NO. INTE0004-100
APPLICATION SERIAL NO. 10/032,311
ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF CONFERENCE REQUEST

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application: Doms *et al.*	**Confirmation No. 6825**
Serial No.: 10/032,311	**Art Unit No.: 1648**
Filing Date: December 21, 2001	**Examiner: Jeffrey S. Parkin**

For: LIPOPARTICLE COMPRISING A PROTEIN AND METHODS OF MAKING AND USING THE SAME

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Dear Sir:

ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF CONFERENCE REQUEST

Pursuant to the Official Gazette Notices dated July 12, 2005 and February 7, 2006, Applicants hereby request a Pre-Appeal Brief Conference. A Notice of Appeal accompanies this request. This request is being filed in response to the Final Rejection dated as mailed October 17, 2006 ("Final Rejection"). Accordingly, it is believed that no extension of time is necessary. If Applicants' belief is erroneous, Applicants hereby petition for any necessary extension, and authorize that any fee for said extension be charged to Deposit Account 50-1275.

Claims 1, 2, and 5-8 are pending. Claims 9-13, 15, 18-35 and 37-49 are withdrawn from consideration. All pending claims were rejected in the Final Rejection. The only rejection remaining is under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Applicants contend that the rejection is based upon numerous legal and factual errors.

Applicants claims are drawn to an isolated virus-like particle ("VLP") comprising an enveloped virus core said virus like particle further comprising a heterologous multiple membrane spanning protein. As Applicants have endeavored to explain repeatedly, their invention is not directed to a lipoparticle comprising a **particular** multiple membrane spanning protein, but rather it is directed to a lipoparticle comprising **any** multiple membrane spanning protein. Applicants' invention allows one of ordinary of skill in the art to study and manipulate multiple membrane spanning proteins of interest in a manner that wasn't possible prior to the present invention, i.e., effectively in their native conformations. Nor is their invention directed to multiple membrane spanning proteins *per se*; Applicants' invention is not the discovery of multiple membrane spanning proteins but, rather, the incorporation of the same in virus-like particles.

In the paragraph bridging pages 4-5 of the Final Rejection, the Office argues that the present application does not satisfy the written description requirement because, in part, the application allegedly "fails to provide any meaningful structural or functional information" concerning the multiple membrane spanning protein. The Office contends that the multiple membrane spanning proteins described in the "working embodiments" are directed toward VLPs that can be directed to virally infected cells, but that "there is no evidence that applicants contemplated making or preparing VLPs comprising non-viral multiple membrane proteins." This factual contention is simply incorrect. Applicants disclose non-viral multiple membrane proteins. For example, in the paragraph bridging pages 25-26 of the application as filed, G-protein coupled receptors in general, mu-opioid receptor, transporters, ion channels, etc., are disclosed as being multiple membrane spanning proteins contemplated by the invention. On page 26, first full paragraph, neuropilin-1 ("NP-1"), a VEGF receptor subtype, is described. VLPs were constructed with NP-1 (See p. 87 of the application as filed, first full paragraph.). Also, even though CCR5, CXCR4, CD4, and MCAT are viral receptors, they have numerous other uses in the particles than just binding virally infected cells. See, for example, Example 3, beginning on page 78 of the application as filed.

The Office further alleges that, although the application describes other multiple membrane spanning proteins, "there is no evidence suggesting that applicants were in possession

of any other **constructs** or that they were **interested** in VLPs expressing any of these [other multiple membrane spanning proteins]." (Emphasis added.) The Office is misapplying the law for satisfying the written description requirement. First, working examples, i.e., actual constructs, are not necessary. *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006). Second, whether or not the Applicants are "interested" in making VLPs comprising any particular multiple membrane spanning protein is irrelevant to a written description determination. However, even if "interest" were relevant, Applicants have clearly shown interest in VLPs comprising any type of multiple membrane spanning protein by disclosing various types of multiple membrane spanning proteins and by claiming the same in the as-filed application.

Relying upon *Fujikawa v. Wattanasin*, the Office again alleges that "providing a 'laundry' list of various membrane spanning proteins does not lead the skilled artisan to any particular protein." The Office continues to misunderstand the invention and, thus, improperly rely upon *Fujikawa*. Again, the invention is not a particular membrane spanning protein. In *Fujikawa*, the issue was whether there was sufficient disclosure of a particular **species**. The court observed that a laundry list of every possible **moiety** "*at every possible position* " is insufficient to constitute a written description of every **species** in the genus. *Fujikawa v. Wattanasin,* 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). The issue was not whether disclosure of all species is a sufficient description of a **genus.** Applicants believe that the Office continues to make this error because it is leaving out the text in italics above.

Regardless, Applicants provide more than just a mere "laundry" list of various multiple membrane spanning proteins and instead disclose the actual making of VLPs comprising different classes of multiple membrane spanning proteins.

The Office also relies on the decision of *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), *inter alia*, to support the requirement that Applicants provide the structure of any multiple membrane spanning protein within the scope of the claim. First, such is not required to satisfy written description.

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by

> disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

MPEP, 2163 II. A. 3. a. ii.

Applicants have complied with the requirements for satisfying written description of a genus as set forth above. First, Applicants have disclosed actual reduction to practice of different species of multiple membrane spanning proteins. The specification discloses the actual reduction to practice of virus-like particles comprising the amino acid transporter (and MLV receptor) MCAT-1 (see, Example 2, page 77) and virus-like particles comprising the G protein-coupled receptors CXCR4 or CCR5 (see, Example 3, page 78, beginning at line 15).

Second, Applicants have disclosed relevant identifying characteristics. Applicants respectfully direct the Office's attention to page 59, beginning at line 7, where a multiple membrane spanning protein is described as a polypeptide that spans the cell membrane at least twice.

As noted above, Applicants' invention is not the discovery of multiple membrane spanning proteins but, rather, the incorporation of such proteins in virus-like particles. In that regard, Applicants' invention is not unlike that in *Capon v. Eshhar*, 418 F.3d 1349, 1359-1360, (Fed. Cir. 2005).

In *Capon,* the claims recited chimeric DNAs (or genes) comprising DNA encoding, for example, a single chain Fv domain of a specific antibody and the transmembrane and cytoplasmic domain of an endogenous protein. *Id.* at 1352-1353. The Board had rejected such claims for lack of written description, arguing that novel genetic material was being described in terms of the functional characteristics of the protein encoded. *Id.* at 1354-1355. The Board, relying upon much of the same precedent relied upon by the Office in rejecting Applicants' claims, was requiring the complete sequence. *Id.* The Federal Circuit overturned the Board's rejection, observing that none of the cases relied upon by the Board required a re-description of what was already known. *Id.*, at 1357-1358. In the present case, as in *Capon*, the Applicants

should not be required to redescribe multiple membrane spanning proteins. *Capon* was recently cited approvingly in another Federal Circuit decision regarding written description. *See Faulkner, supra.*

The present claims and specification constitute "more than a wish for possession" or a "laundry list" as the Office alleges. In contrast to the cases cited by the Office, the present application discloses the incorporation of a diverse set of multiple membrane proteins into virus-like particles such that one of ordinary skill in the art would recognize that the Applicants were in possession of the genus at the time the application was filed.

Accordingly, the skilled artisan would consider that Applicants were in possession of the claimed invention at the time of filing. Thus, for the reasons set forth above, Applicants respectfully submit that the specification as filed provides sufficient written, and, therefore, respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph.

Respectfully submitted,

Doreen Yatko Trujillo
Registration No. 35,719

Date: December 18, 2006

COZEN O'CONNOR, P.C.
1900 Market Street, 7th Floor
Philadelphia, PA 19103-3508
Telephone: (215) 665-5593
Facsimile: (215) 701-2005